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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,091	12/16/2004	Giancarlo Cravotto	48239	5511
1609 7590 01/27/2009 ROYLANCE, ABRAMS, BERDO & GOODMAN, L.L.P. 1300 19TH STREET, N.W. SUITE 600 WASHINGTON,, DC 20036			EXAMINER CARR, DEBORAH D	
			ART UNIT 1621	PAPER NUMBER
			MAIL DATE 01/27/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/518,091

Applicant(s)

CRAVOTTO, GIANCARLO

Examiner

DEBORAH D. CARR

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-19, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17-18 is/are allowed.
- 6) ☒ Claim(s) 13-16, 25 and 26 is/are rejected.
- 7) ☒ Claim(s) 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments, see pages 7-8, filed 27 August 2008, with respect to the rejection(s) of claim(s) 13-16, 17-19, 25 under 35 USC§112, 2<sup>nd</sup> paragraph have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.
2. Applicant's arguments filed 27 August 2008 regarding claims 25-26 rejected under 35 USC§112, 1<sup>st</sup> paragraph have been fully considered but they are not persuasive. The rejection as been maintained.
3. Upon further consideration, a new ground(s) of rejection is made in view of Murakami et al. and JP 58144317.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 25-26 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant argues claims 25-26 are enable to one of ordinary skill in the art based on the knowledge of the skilled artisan, the specification and the prior references.

As stated previously, polyunsaturated fatty acids and polycosanols such as EPA, DHA, and hexacosanols maybe known to treat hypocholesterolemia, one cannot apply what is conventionally known the instant compounds. EPA & DHA contain a minimum of 5 double bonds and no substitutions. The fatty acid based compounds in claims 25-26 are not required to contain unsaturation, are substituted and cannot be considered structurally close enough to transpose the pharmacological properties of EPA or DHA.

The polycosanols are comprised primarily of the four primary aliphatic alcohols, tetracosanol, hexacosanol, octacosanol and triacontanol. These are all long chained fatty alcohols containing no substitution or unsaturation. The primary alcohol based compounds in claims 25-26 contain unsaturation, are substituted and therefore cannot be considered structurally close enough to transpose the pharmacological properties of the polycosanols used to treat hypocholesterolemia.

While the compounds may be of the same class of compounds such as alcohols or fatty acids, there is not enough structural similarity to extrapolate that the instant compounds can treat hypocholesterolemia.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 13-16 rejected under 35 U.S.C. 102(b) as being anticipated by Murakami et al.

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Murakami et al. teaches compounds reading on the instant invention that are applicable as pharmaceutical compositions in the treatment of gastric ulcers. The compound in particular is 2,6,10,14,18,22,26-Octacosaeptaen-1-ol, 3,7,11,15,19,23,27-heptamethyl-, (2E,6E,10E,14E,18E,22E)- (CA INDEX NAME), RN – 32304-16-8.

8. Claims 13-15 rejected under 35 U.S.C. 102(b) as being anticipated by JP 58144317.

JP'317 teaches compounds reading on the instant invention that are applicable as pharmaceutical compositions as neoplasm inhibitors. The compound in particular is 2,6,10,14,18,22,26-Octacosaeptaen-1-ol, 3,7,11,15,19,23,27-heptamethyl-, (2Z,6Z,10Z,14Z,18E,22E)- (CA INDEX NAME), RN 5905-41-9.

***Allowable Subject Matter***

9. Claims 17-18 are allowed.

10. Claim 19 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH D. CARR whose telephone number is (571)272-0637. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah D Carr/  
Primary Examiner  
Art Unit 1621

Ddc